

Appl. No. 09/978,428 (Docket No. B0048-US02)  
Resp. dated 02/13/2004  
Reply to OA of Nov. 14, 2003

### REMARKS

In response to the Office Action of November 14, 2003, Applicants present this Request for Reconsideration. No claims are newly amended.

Claims 1-3 and 6-8 stand rejected by the Examiner under 35 USC 103(a) as being unpatentable over WO95/01842. In this rejection the Examiner makes the assumption that "In order to lead a first fraction into a first inner bag, a clamp valve on a branched tube leading to a second inner bag must be closed . . .". This is an assumption not supported by the disclosure of WO95/01842. No where in the reference does it state that valves 38 and 39 are closed during the filling procedure. Lines 7 to 12 of page 9 of WO95/01842 only indicate that the clamp valves are controlled by the program operation of the centrifuge and/or photocells which detect the placement of the boundary surface of the phase in the connection tube. During the filling procedure, when the outer container is filled with fluid there would not necessarily be any boundary surface of the phase in tube 3. Applicants note that tube 6 is closed after filling but there is no disclosure that tube 3 is closed by either clamp valves 38 and 39. To further support that the Examiner's assumption is erroneous, Applicants note that the middle paragraph of page 9 further calls for the alternative use of a one-way valve.

From this assumption, which is not based on any disclosure in the WO95/01842 patent, the Examiner goes on to assume that "a clamp valve on a branched connector tube leading to a second inner bag must be activated to open position from previously closed position . . ." (page 9 of the reference). Again this is an assumption of the Examiner not supported by the reference.

For example, there is another possible assumption that the Examiner has not considered and that is the assumption that the clamps are normally opened and are only closed after each inner bag is filled.

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If the Examiner persists with this rejection Applicants request that the Examiner particularly point out in WO95/01842 where the reference discloses that the "step of transferring said fraction through said outlet tube occurs upon activation of said centrifuge valve into open position during centrifugation" (Applicants' Claim 1).

The Examiner assumes that the step above is a necessary step to successfully transfer thrombocyte-rich plasma from a processing bag 1 to a storage bag 2. However, in page 10 of WO95/01842 as well as throughout the PCT application the transfer to the inner bag is described similar to as follows: "A pressure is brought to bear thereafter on the outer bag and the thrombocyte suspension is pressed during an on-going centrifugation via the tube 3 to the inner bag 2" (Figure 11; and lines 14-17). There is no disclosure of the opening of a clamp valve on tube 3 during centrifugation and there is no disclosure in WO95/01842 that any clamp valve on tube 3 is not already open prior to the filling of the outer bag.

Further, there is no teaching in WO95/01842 that the opening of such clamp valve would be an obvious modification since the reference does not imply that such a step is needed.

Claims 9-11 stand rejected under 35 USC 103(a) as being unpatentable over WO95/01842 in view of US Patent No. 5,116,308, Hagiwara. Claims 9-11 depend from Claim 1 and it is Applicants' position that these claims should be allowable for the reasons set forth above with respect to Claim 1.

The Examiner has responded to Applicants' previous arguments by stating that when double inner bag chambers are used with clamp valve 38, 39, at least one clamp valve must be closed so that only one inner bag is filled at a time. Applicants assume the Examiner means that the clamp on the second-to-be-filled inner bag must be opened during centrifugation. However, the two-inner-bag process, as described on pages 11 and 12, although indicating that the plasma or supernatant are pressed into the first inner bag during rotation or centrifugation, the reference is silent as to whether the second inner bag is filled during centrifugation. The reference is also silent as to the action of the clamps. Thus, if the valve to the second inner bag is opened (though

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the reference does not state that it is opened) such opening could occur "thereafter" which could be after centrifugation. Thus it is Applicants' belief that the reference allows more variables than the "must" assumptions of the Examiner. The reference also refers to after centrifugation movement of fractions at the bottom of page 1, continuing on page 2.

It is believed that no fee is due for the filing this Request for Reconsideration. However, please charge Deposit Account No. 03-2316 if any other fee is determined to be necessary, and consider this statement as authorization to charge any such fee to said account.

It is believed that this application is now in condition for allowance and such passage to issue is respectfully requested. If the Examiner has any questions, or if prosecution can be expedited in any manner by a telephone conference, the Examiner is urged to call the undersigned's representative, Laura Butterfield at (303) 231-4270, Patent Counsel for Gambro, Inc., as the undersigned attorney will be out of the country until March 1, 2004.

Respectfully submitted,

2/13/2004

Date

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